International Market Insight

The new EU chemicals regulation- REACH

U.S. Commercial Service
U.S. Mission to the European Union
2 March 2006

Introduction

This report outlines the new EU chemicals policy known as REACH. Proposed by the European Commission in October 2003, REACH stands for the registration, evaluation and authorization of chemicals. REACH adoption and entry into force is expected for the end of 2006/ early 2007. At the time of writing, the latest version of the REACH regulation is the Council Political Agreement of December 13, 2005, which is the basis for this report. The European Parliament also adopted an amended text that must be reconciled with the Council text during the second reading, which will take place in summer 2006. As REACH is still in draft form, this report is not meant as a guide for compliance. It has been drafted for U.S. exporters to Europe, in particular for small and medium sized enterprises, to inform them about this major new piece of legislation and to help them prepare for REACH. It gives an introduction to the main REACH requirements and provides links to more comprehensive sources of information.

Registration

Registration is the main stage of REACH. It will apply to approximately 30,000 substances currently marketed in the EU and will involve submitting a registration to the European Chemicals Agency, to be created in Helsinki in 2008. Manufacturers and importers into the EU of chemicals will have to submit information on the properties of their substances, their uses and safe ways of handling them in a technical dossier (for substances of 1 ton or more per year), coupled with a chemical safety report for substances above 10 tons (see box 1). These provisions also apply, under certain conditions, to manufacturers and importers into the EU of preparations (mixtures of substances) and articles (finished products). See box 2 and 3.

Safety information will have to be passed to clients so that they can use substances safely. Information to be communicated along the supply chain, including how to draft safety data sheets for the EU, is described in articles 29 to 33 of the REACH regulation.

Some chemicals will be exempted from registration under REACH. They include substances below 1 ton, pharmaceuticals, pesticides, biocides and polymers. However, monomers have to be registered (article 5.3). More exemptions are included in annex II and III of the REACH regulation.

Manufacturers and importers must be established in the EU in order to register. Non-EU manufacturers can appoint an EU-based representative for the purpose of registration (see REACH article 6.a on the only representative of a non-Community manufacturer). The EU representative can be a subsidiary, a consultant or any natural or legal person with experience in chemical handling.

Deadlines and information requirements for registration will depend on volume. Higher volume chemicals (above 1000 tons) will have to be registered first (3 years after REACH

entry into force: by 2010) and will require additional testing. For substances between 100 and 1000 tons, the deadline for registration is up to 6 years. Low volume chemicals (between 1 and 100 tons) will have to be registered later (11 years after REACH entry into force: by 2018) with reduced information requirements (article 21). All tonnages refer to metric tons.

Pre-registration: To benefit from these registration deadlines of up to 11 years, pre-registration information must be submitted to the Agency. A single pre-registration deadline, irrespective of tonnage, is planned to permit joint submission of registrations by multiple registrants and data sharing. Pre-registration is recommended as pre-registered substances can continue to be marketed before completing the full registration. Pre-registration facilitates partnering for joint registrations to reduce costs. Companies should be aware that the pre-registration period will be extremely short - 6 months, which will most likely begin in Spring 2008, when the Agency is in place (12 months after REACH entry into force) and before the pre-registration deadline ends (18 months after REACH entry into force). Article 26 details information to be submitted for pre-registration (see box 1).

Rules on joint submission of registration ("One substance, One registration") are set in article 10. It foresees mandatory joint data submission with possibilities to opt-out for the following reasons: disproportionate cost, disclosure of commercial secrets or disagreement on selecting data. Derogations would have to be justified in the registration dossier (article 10.2 bis).

Rules on data sharing are detailed in articles 23 to 26. Data sharing is mandatory. It is always mandatory for animal testing. It is mandatory on request from previous registrants for non-animal testing (article 25.1). Relevant compensation is also required.

The sharing and joint submission of information will concern technical data and in particular information related to the intrinsic properties of substances. It will not imply exchanging information on market behavior, in particular as regards production, sales or market shares (article 23.2).

Pre-registrations and registrations will have to be submitted on-line. The agency will make non-confidential data available to the public over the Internet (see article 116 on confidentiality). All registrations will be checked by the Agency for completeness.

Failure to register substances will mean that the substance, or the preparation or the article containing it, cannot be exported to Europe.

Box 1 - Documents to prepare for registration:

For the agency:

◇ **Pre-registration** (above 1 ton), article 26:

1. The name of the substance
2. The name of the contact person
3. The envisaged deadline for the registration/ tonnage band

◇ **Technical dossier** (above 1 ton), article 9:

1. The identity of the manufacturer or importer
2. The identity of the substance
3. Information on the manufacture and uses of the substance
4. The classification and labeling of the substance
5. Guidance on safe use of the substance
6. Summaries of the required information:
   - 1-10 tons: Annex V
   - 10 – 100 tons: Annex V and VI + Chemical safety report
   - 100 – 1000 tons: Annex V, VI and VII + Chemical Safety report
   - 1000 tons or more: Annex V, VI, VII and VIII + Chemical safety report

7. Robust study summaries
8. Proposals for new testing
9. A justification for confidential information that should not be made available on the internet.

◇ **Chemical safety report** (above 10 ton): see article 13 and annex I

The chemical safety report documents the chemical safety assessment which includes an analysis of hazards, and for substances classified as dangerous, an assessment of exposure ("exposure assessment") and an assessment of risks for health and the environment ("risk characterization"). When the substance is classified as dangerous, the chemical safety report must identify appropriate risk management measures for all uses identified by the manufacturer or the importer and their downstream users.

For downstream users:

◇ **Safety Data Sheet** (no tonnage threshold): see article 29 and annex I a

The European Commission is drafting guidelines on how to draft technical dossiers, chemical safety reports and safety data sheets: http://ecb.jrc.it/REACH/RIP_PROJECTS

Box 2 - Substances in articles (finished products):

Substances incorporated in articles, such as chemicals in toys, textiles or computers, have to be registered if they are present in the article in quantities over 1 ton per year, and are "intended to be released during normal or foreseeable conditions of use" (article 6.1). A classic example of a substance intended to be released during use is the ink in a pen. This provision does not apply to substances that have already been registered for that use. See box 1 for information to be submitted for registration.

If the substance is not intended to be released, for example dye in clothing, the substance will have to be notified if it is of "very high concern" (article 54 on substances subject to authorization), is present above 1 ton and above the concentration of 0.1%. Substances are exempt from notification if the producer can exclude any exposure, during normal conditions of use including disposal (article 6.2). See article 6.3 for information to be submitted for notification. The Agency may require the producers and importers concerned to register such notified substances.

The European Commission is drafting guidelines to help companies identify if their substances incorporated in articles are subject or not to registration or notification. They are available at: http://ecb.jrc.it/REACH/RIP_PROJECTS

Box 3 - Registering substances in preparations (mixtures of substances)

Since REACH is substance based, substances included in the preparation (ex: a paint) and not the preparation itself have to be registered. The same registration requirements apply to substances on their own and to substances in preparations. Technical dossiers (above 1 ton) and chemical safety reports (above 10 tons) have to be prepared for each substance included in a preparation. However, no chemical safety assessment is needed if substances are in low concentration in a preparation (article 13 and annex IB).

To view the articles referenced above, see the REACH text (Council version): http://register.consilium.eu.int/pdf/en/05/st15/st15921.en05.pdf

For more detailed information on registration, see the below Commission documents.

- Draft guidance documents: http://ecb.jrc.it/REACH/RIP_PROJECTS
- FAQs: http://europa.eu.int/comm/environment/chemicals/pdf/qa_reach_part2-2004_11_22_en.pdf

Evaluation

At the evaluation stage, the Agency will examine, in more detail, registration dossiers for substances above 100 tons. This further examination would apply to approximately 5,000 substances. As a result, registrants may have to provide additional information (Dossier evaluation: see articles 38 – 43). Individual substances may also be evaluated which may lead to these substances being restricted at EU level or subject to authorization (Substance evaluation: see article 43 a – 46).

Authorization

Authorization is required for substances qualified as "substances of very high concern". These substances include carcinogens and chemicals that are mutagenic and toxic to reproduction (CMRs); substances which are persistent, bioaccumulative and toxic (PBTs and vPvBs); endocrine disruptors and substances "which give rise to an equivalent level of concern" (article 54). It is estimated that 1,500 substances will require authorization.

The authorization stage of REACH is independent from registration and evaluation and applies without limits of tonnage. Substances manufactured or imported under the one ton per year limit may also be subject to authorization even if they do not have to be registered.

Authorization is use-specific. It will be granted if the applicant can show that the risks associated with the uses of that substance are adequately controlled (article 57.2). If this is not the case, it must be shown that socio-economic benefits outweigh the risk to human health or the environment and that there are no suitable alternatives. All applications for authorization must be accompanied by an analysis of substitutes. Authorizations will be subject to a time-limited review determined on a case-by-case basis. No authorization based on adequate control can be granted to most CMRs, and all PBTs and vPvBs but it is still possible to grant authorization on the grounds of socio-economic benefits.

Chemicals subject to authorization will be listed in annex XIII of the REACH regulation based on a priority list established at EU level. Priority would be given to substances with PBT or vPvB properties, wide dispersive use or high volumes (article 55.3). Once a substance is included in annex XIII, companies must apply for authorization of each use of the substance within the deadlines set. A candidate list of substances meeting the criteria of article 54 on authorization will also be created for the eventual inclusion of these substances in annex XIII (article 56.1). It is feared that this candidate list will have a black list effect and that downstream users will stop using such substances even before authorization is required.

The authorization procedure not only applies to substances in preparations but also substances present at low concentrations in preparations are exempt from authorization (see article 53.7).

Box 4 – Applying for authorization

Applications for authorization must be made to the European Chemicals Agency They must include (article 59):

- the identity of the substance
- the name of the applicant
- a request for authorization specifying for which use
- a chemical safety report if not submitted for registration
- an analysis of the alternatives considering their risks and the technical and economic feasibility of substitutes

II.5 Restrictions (Title VIII – article 64 – 70)

Any substance on its own, in a preparation or in an article may be subject to restrictions EU-wide. Member States can make a proposal to the Agency to ban or restrict the marketing and use of a substance. Based on the opinion from the Agency, the Commission will make the final decision on the restriction of a substance. The Restrictions stage of REACH is similar to the existing directive on restrictions on the marketing and use of certain dangerous substances and preparations (Directive 76/769/EEC). It is important to respect restrictions in accordance with annex XVI and XVII.

The Restrictions and Authorization stages of REACH are mutually exclusive. A substance that is restricted at EU level cannot be authorized for a particular use.

III Preparing for REACH

REACH is still in draft form. Although the European Parliament, Council and Commission have agreed on many parts of the text, there are some portions that could change in the second reading. The European Commission is presently working on guidance documents and will entertain stakeholder input until they are formally adopted by the Agency when it starts operating in 2008. Companies who have the resources may want to examine current drafts and comment on procedures that may be disproportionately costly or burdensome. To view the latest version of the guidance documents, see: http://ecb.jrc.it/REACH/RIP_PROJECTS

Pre-registration will be the first deadline under REACH expected to begin in Spring 2008. It is advisable to start preparing for REACH now.

Companies should start looking at available information and make an inventory of their substances exported to Europe, either on their own, in preparations and/ or in articles.

They should determine if their substances are covered or exempted from REACH. If they are regulated, they should look at their properties, uses, classification and determine annual volumes exported to the EU. Volumes may be determined by an average of the past three years, however, no decision has yet been formalized.

One may also want to make an inventory of available studies, in particular tests involving animals, and update safety data sheets so that they comply with REACH requirements.

Substances that may be subject to authorization for the EU market should be identified.

In addition to collecting existing information, it is also advised to engage early in a dialogue with suppliers and customers, in particular to identify uses of substances and volumes.

We also recommend that U.S-based companies consider the option of an EU representative to do the registration on their behalf.

Companies may also want to look at the costs associated with REACH such as the administrative costs for registration and authorization as well as the costs for joining a consortium. Various studies have assessed the cost of REACH and forecasted that REACH may lead to substances being withdrawn from the market because of high testing costs. Downstream users of a substance may want to ensure that their suppliers will continue to produce a particular substance and register it.

Early preparation should prevent a dossier from being blocked because it is incomplete or not submitted within the deadlines. Ultimately early preparation will help avoid a situation where a substance, a preparation or an article cannot be exported to Europe or its marketing delayed.

The European Commission is currently preparing guidelines for industry on how to comply with REACH: http://ecb.jrc.it/REACH/RIP_PROJECTS

The Commercial Service at the U.S. Mission to the EU has set up a REACH webpage on its webiste at: http://www.buyusa.gov/europeanunion/reach.html. As REACH develops, it will include the latest versions of the REACH text, the European Commission guidelines and any other relevant information to help American companies prepare and fully comply with REACH.

Additional sources of information

REACH regulation (Political Agreement of the European Council)
http://register.consilium.eu.int/pdf/en/05/st15/st15921.en05.pdf

European Commission – DG Environment and DG Enterprise:
http://europa.eu.int/comm/environment/chemicals/reach.htm
http://europa.eu.int/comm/enterprise/reach/index-en.html

Commission FAQs on REACH:
http://europa.eu.int/comm/environment/chemicals/pdf/qa_reach_part2-2004_11_22_en.pdf

Commission guidance documents (See RIP-3: Guidance documents for industry):
http://ecb.jrc.it/REACH/RIP_PROJECTS

U.S. Government views on REACH

The U.S. government has engaged early on REACH, providing comments on the legislation. See the US Mission website: http://useu.usmission.gov/

Contact us

The U.S. Commercial Service at the U.S. Mission to the European Union is located at Boulevard du Regent 27, Brussels B-1000, Belgium, and can be contacted via e-mail at: brussels.ec.office.box@mail.doc.gov;
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